

REMARKS

The present amendment is submitted in response to the Office Action mailed March 18, 2008. Claims 1-26 and 31 are currently pending. By the present amendment, claims 1 and 17 have been amended; claims 27-30 having been previously cancelled. No new issues are presented by these amendments. Prompt and favorable consideration of these claims is earnestly sought.

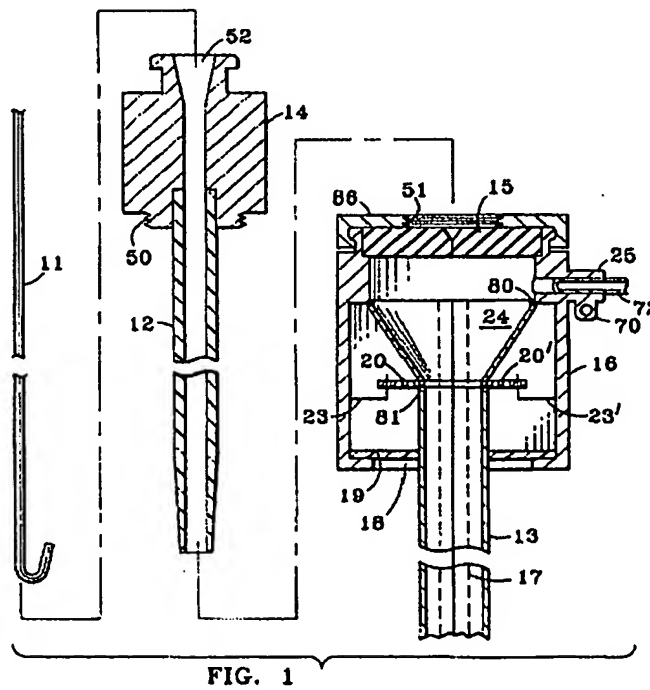
Claims 1-3, 7-9, 11, 12, 17-20, 23-25 and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,827,227 to Delago (hereinafter, "Delago") in view of U.S. Patent No. 5,911,714 to Wenstrom, Jr. (hereinafter, "Wenstrom"). According to the Examiner, Delago teaches a sheath system and a method of use substantially as claimed, except for disclosing a second thread is formed along substantially an entire length of the tubular member. The Examiner relies on Wenstrom for such disclosure.

Delago fails to teach or disclose a sheath system including, *inter alia*, an expansion assembly including a tubular member, "the tubular member having an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, the second thread being arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath," as recited in amended claim 1.

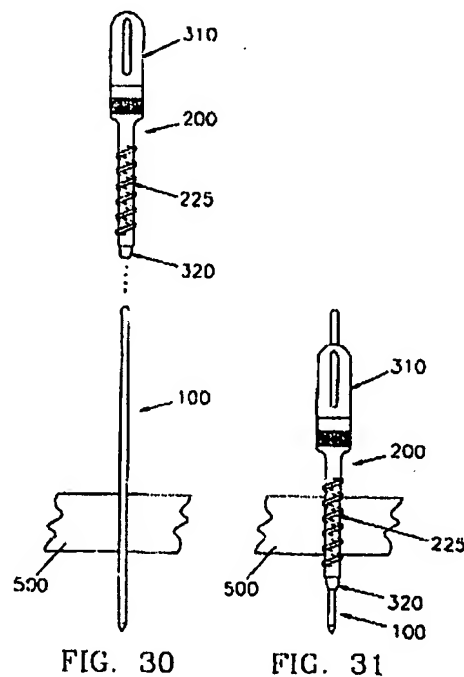
Delago further fails to teach or disclose a method of using a sheath system including, *inter alia*, the steps of "introducing an expansion assembly, having a tubular member with an

outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient, the introduction including engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath,” as recited in amended claim 17.

With reference to FIG. 1, reproduced herein below, Delago discloses a catheter apparatus 10 including a guide wire 11, a dilator 12 and a sheath 13. Dilator 12 is a substantially tubular member having a housing 14 for securely engaging dilator 12 within sheath 13. Threads 50 are formed on housing 14 for engaging threads 51 formed in cap 86 of sheath 13.



The Examiner relies on Wenstrom for the disclosure of a thread formed along substantially an entire length of the tubular member. However, with reference to FIGS. 31 and 32, reproduced hereinbelow, Wenstrom discloses a cannula housing 200 including a helical thread 225 formed on the outer surface of distal portion 205. Helical thread 225 is configured to directly engage tissue 500 such that twisting of cannula housing 200 causes thread 225 to set securely into the tissue 500. Helical thread 225 is not configured to engage a first thread formed on any dilation assembly, much less to engage a first thread of a tubular sheath to axial advance the tubular member along the entire length thereof through the tubular sheath, as recited in claim 1.



Contrary to the Examiner's assertion, Applicants submit that it would not have been obvious to combine the helical thread of Wenstrom, configured for engaging tissue, with the

dilator of the radially adjustable catheter apparatus of Delago, to expand the sheath as the dilator is inserted through the sheath.

Therefore, since Delago does not teach or disclose dilator 12 having threads 50 formed along substantially an entire length of the tubular member, and it would not have been obvious to combine the tissue engaging thread of Wenstrom with the sheath expanding dilator of Delago, it is respectfully submitted that claims 1 and 17 are patentable over Delago in view of Wenstrom and the rejection of the claims 1 and 17 as being unpatentable under 35 U.S.C. §103 over Delago in view of Wenstrom, has been overcome.

Since claims 2-3, 7-9, 11 and 12 depend from claim 1 and claims 18-20, 23-25 and 31 depend from claim 17, and each contains all the features of respective claims 1 and 17, for at least the reasons presented above, claims 2-3, 7-9, 11, 12, 18-20, 23-25 and 31 are also allowable under 35 U.S.C. § 103 over Delago in view of Wenstrom.

Claims 1-9, 11, 12, 14 and 15-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,080,174 to Dubrul et al. (hereinafter, "Dubrul") in view of Delago in further view of Wenstrom. According to the Examiner, Dubrul teaches a sheath system substantially as claimed, including a dilation assembly and an expansion assembly. However, as the Examiner duly notes, Dubrul fails to teach that the dilation and expansion assemblies include first and second threads, respectively, and Dubrul and Delago fail to teach that the second thread is formed along substantially an entire length of the tubular member. As such, the Examiner relies on Delago to teach the use of common first and second threads for attaching components in a sheath system, and on Wenstrom to teach the second thread formed along substantially an entire length of the tubular member.

As discussed above, Delago fails to teach or disclose the thread being formed along a substantial portion of the tubular member. Instead, with reference back to FIG. 1 of Delago, reproduced hereinabove, thread 50 of dilator assembly 12 is formed on housing 14, not on the tubular member, and only extends a portion of a length of housing 14. Thus, Dubrul, taken alone or in any proper combination with Delago, fails to suggest or disclose a dilator assembly including a tubular member, "the tubular member having an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, the second thread being arranged for engaging the first thread to axially advance the tubular member along the entire length thereof through the tubular sheath," as recited in amended claim 1.

Delago further fails to teach or disclose a method of using a sheath system including, inter alia, the steps of "introducing an expansion assembly, having a tubular member with an outer surface defining a second thread formed along substantially an entire length of the tubular member from a location at least in close proximity to a distal end of the tubular member to a location in close proximity to a proximal end of the tubular member, into the lumen of the dilation assembly to radially expand the lumen of dilation assembly and the opening in the body of the patient, the introduction including engaging the first thread with the second thread to axially advance the tubular member along the entire length thereof through the tubular sheath," as recited in amended claim 17.

As discussed above, contrary to the Examiner's assertion, it would not have been obvious to combine the tissue engaging thread of the cannula system of Wenstrom with a

dilation assembly for expanding a tubular sheath. Therefore it is respectfully submitted that claims 1 and 17 are patentable over Dubrul in view of Delago and further in view of Wenstrom, and that the rejection of the claims 1 and 17 under 35 U.S.C. § 103 as being unpatentable over Dubrul in view of Delago and Wenstrom, has been overcome.

Since claims 2-9, 11, 12, 14 and 16 depend from claim 1, and claims 18-26 depend from claim 17, and each contain all of the features of respective claims 1 and 17, for the reasons presented above, it is respectfully submitted that claims 2-9, 11, 12, 14, 16, and 18-26 are also allowable.

Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Delago/Wenstrom or the combination of Dubrul/Delago/Wenstrom. As discussed above, none of Delago, Dubrul, nor Wenstrom, taken alone or in any proper combination suggest or disclose all the features of independent claim 1. Since claim 10 depends from claim 1, for at least the reasons claim 1 is patentable, claim 10 is also patentable.

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dubrul/Delago/Wenstrom as applied to the 103(a) claim rejection above, and further in view of U.S. Patent No. 6,767,355 to Frova et al. (hereinafter, "Frova").

Frova discloses a tracheostomy dilator for widening a tracheal opening. The tracheostomy dilator includes threads on an outer surface that are configured to engage tissue. There is no suggestion, motivation or teaching to use the tracheostomy dilator for any purpose other than to widen an opening in the trachea to access the airway of a patient. A person of ordinary skill in the art of surgical instrument introduction systems, for accessing an

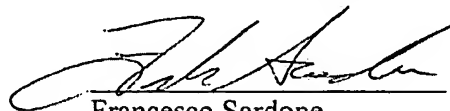
abdominal cavity, would not look to a device for accessing an airway of a patient. Furthermore, as disclosed in column 4 lines 27-31 of Frova, the first thread 35 is formed such that it has automatic cutting properties. This is necessary for the engagement of tissue wherein the tip creates an opening in the tissue. Incorporation of a dilator including a cutting thread formed along any portion thereof would result in the dilator cutting or shredding the tubular sheath upon insertion of the dilator assembly, thereby rendering the system inoperable. Therefore, the combination of Frova with Dubrul/Delago/Wenstrom is improper and the rejection of Claim 13 under 35 U.S.C. § 103(a) should be withdrawn.

In view of the foregoing remarks, Applicants submit that all of the claims are in proper format, are patentably distinct from the prior art of record, and are in condition for allowance.

The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



Francesco Sardone
Reg. No. 47,918
Attorney for Applicants

CARTER, DELUCA, FARRELL & SCHMIDT, LLP

445 Broad Hollow Road, Suite 420
Melville, New York 11747
Telephone: (631) 501-5700
Facsimile: (631) 501-3526
FS/JJR